

MedVision Inc.
North Brunswick, NJ
February 1, 1997

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K 961343

Section 2

510 (k) Summary

Device Trade Name

MedVision Personal Monitor Models A and B

Common /Usual Name

Head Mounted Display
Virtual Display Device

Classification Name

Accessory to Endoscopes

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Predicate Device

Trade Name: Head Mounted Display
Manufacturer: Vista medical Technologies
5451 Avenida Encinas, Suite A
Carlsbad, CA 92008
510 (k)#: K961800

Summary Preparation Date: February 1, 1997

Statement of Intended Use

The MedVision Personal Monitor Models A and Models B are intended to display video image while mounted on the user's head.

Device Description

In endoscopic procedures the conventional video monitors are placed away from the site of the operation. As a result, the surgeon has to constantly divide his/her attention between the conventional monitor that shows the endoscopic image and the site of the operation. The remote location of the monitor and its orientation in the surgical setting have an effect on both the doctor's perception of the surgical field, and the difficulties encountered when interacting with it. Much of the difficulty encountered by a surgeon when learning the techniques videoendoscopy, relate to the disconnection between instrument movements on the video monitor and their hand movements. With the displacement and axial rotation of the monitor, the doctor must relearn the image to tissue relationship at each procedure, and with each manipulation of the camera. With

this decoupled image, the hand-eye coordination of the doctor suffers. For example, with a 90 degree rotation of the camera, an intended movement South North direction, will result in a display movement in an East to West direction, presenting the doctor with a working field that is difficult to comprehend.

The MedVision Personal Monitors project a high resolution color video image that appears in a the surgeon's line of sight in a viewing angle comparable to watching a 26" television from 2 meters (6.5 feet) away. The video image is see-around; it blocks only the area the image appears, otherwise users are free to view the surrounding environment. The MedVision Personal Monitors provide an added convenience to surgeons compared to conventional monitors. They enables the surgeon to maintain the endoscopic image in the surgeon's line of site regardless of where he/she is looking. The MedVision Personal Monitor Model A and Model B can receive video signals from any video source. The signals are converted in the controller unit into signals the driving electronics of LCD/AMEL displays require.

The MedVision Personal Monitors (MPM) Model A and Model B are monoscopic binocular displays with a relatively narrow field of view. The MPMs take standard video signals and display them on a small TFT LCD display (Model A) or AMEL display (Model B) that can be connected to any standard video source. The MPM consist of a monitor block, eyeglasses and controller box. The monitor block contains the display, for MPM Model A only, a backlight and its driver for the LCD, and a system of lenses and mirrors that project the display image onto the retina of the eyes. The light beams coming from the display are reflected in two directions by dividing mirrors placed in front of the display. The monitor block has a mounting slot that fits into the vertical nose piece of the eyeglasses. The controller box contains the video input demodulator unit and the driving electronics of the LCD/AMEL display. The LCD/AMEL direct display control signals are sent through a flexible shielded cable to the displays.

The eyeglasses have adjustable temple pieces and each unit comes with a commercially available 9V DC adaptor with low EMI..

All components and accessories of the device are marketed as non-sterile.

Device Comparison

The MedVision Personal monitor Models A and B are substantially equivalent to the display component of Vista Medical Technologies' Head Mounted Display, which received clearance from FDA on September 11, 1996 (K 961800). The MedVision Personal Monitor Model A and Model B are binocular monoscopic displays with a single LCD display (Model A) and single AMEL display (Model B). The Vista Medical Technologies' Head Mounted Display has two AMLCDs and it is a monoscopic/stereoscopic display. While the predicate device has large field of view and low apparent resolution, the MedVision Personal Monitors have relatively narrow field of view and relatively higher and apparent resolution. The MedVision Personal Monitors are monoscopic displays that do not need the large virtual distance, large field of view to create the stereoscopic immersion as opposed to Vista's HMD. The tradeoff for the large field of view is the reduction in apparent resolution.

Safety

The MedVision Personal Monitors Model A and Model B are designed, manufactured and tested in compliance with IEC-601-1, IEC-601-2, and IEC 1004-3.

The eyeglasses will have polycarbonate lenses to ensure high resistance to impact and scratch.

When compared to the predicate device the MedVision Personal Monitors Model A and Model B do not incorporate any significant change in intended use and technological characteristics that could affect the safety or effectiveness.